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10/520,685

05/27/2005

Allan Otto Fog Lihme

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22428 7590 04/04/2008  
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EXAMINER

HINES, JANA A

ART UNIT

PAPER NUMBER

1645

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,685	<b>Applicant(s)</b> LIHME ET AL.	
	<b>Examiner</b> JaNa Hines	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-12 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-12 and 15-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/10/05 &amp; 9/20/05</u> .                                   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Amendment Entry***

1. The amendment filed January 4, 2008 has been entered. Claims 1, 13 and 14 are canceled. Claims 3-8, 10-12, 15-26 have been amended. Claims 27-28 have been newly added. Claims 2-12 and 15-28 are under consideration in this office action.

### ***Election/Restrictions***

2. Claims 1 and 13-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 4, 2008.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on January 10, 2005 and September 20, 2005 were filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

4. Claims 2-12, 19, 24 and 28 are objected to because of the following informalities:

a) Claim 2 recites a “....harmful substances responsible of inducing sepsis...” It appears that the wording of the claim is inappropriate. Therefore, clarification is required.

b) Dependant claims 3-12, 19, 24 and 28 refer to "A method..." however the suggested claim language is to use of the article "The." Therefore the suggested claim language is "The method." Appropriate correction is required.

c) Claims 3 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims fail to add any active method steps to the claims. Appropriate clarification is required to overcome the rejections.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-12 and 15-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) The term "being effected" in claims 2 and 27-28 is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is "being effected" by the column assembly. Thus the metes and bounds of the term are unclear.

b) Regarding claims 5, 12, 15, 18 and 25, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

c) Regarding claims 5, 11, 18 and 24, the phrase "preferably" "most preferably" and "most preferred" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05.

d) Regarding claims 12 and 25, the phrase "i.e." renders the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

e) Regarding claims 4 and 26, the phrase "in particular" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05.

f) Claims 11 and 24 recites alternative limitations which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language.

6. Claims 2 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the

steps. See MPEP § 2172.01. The omitted steps are: There is no contact step between the affinity specific molecule and the gram-negative or gram-positive bacteria. There is no correlation step which correlates treating blood by passing the blood through the column assembly and acquiring an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by gram-negative or gram-positive bacteria.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 2-9, 11-12, 15-22 and 24-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Lihme (WO 02/053251 published July 11, 2002).

Claim 2 is drawn to an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by Gram-negative or Gram-positive bacteria in a mammal, said extracorporeal adsorption method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for:

i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or

Art Unit: 1645

harmful substances derived from said Gram-positive bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed.

Claims 3 and 17 are drawn to the treated blood is capable of being reinfused into the same mammal. Claims 4 and 26 drawn to the adsorption column assembly being adapted for fluidized bed adsorption, in particular stabilized fluidized bed adsorption.

Claims 5 and 18 are drawn to the method wherein the particles have a density of at least 1.3 g/ml and a mean diameter in the range of 5-1000  $\mu\text{m}$ , such as a density of at least 1.5 g/ml and a mean diameter in the range of 5-300  $\mu\text{m}$ , preferably a density of at least 1.8 g/ml and a mean diameter in the range of 5-150  $\mu\text{m}$ , and most preferred a density of more than 2.5 g/ml and a mean diameter in the range of 5-75  $\mu\text{m}$ .

Claim 6 is drawn to the mammal being a human being.

Claims 7 and 20 are drawn to the affinity specific molecule is selected from the group consisting of immunoglobulins, peptides, oligonucleotides, receptor proteins, antibiotics, and lectins. Claim 8 and 21 are drawn to two or more different affinity specific molecules are present on particles within the adsorption medium.

Claim 9 and 22 are drawn to the affinity specific molecules being selected from immunoglobulins. Claims 11 and 24 are drawn to the affinity specific molecule being selected from the group consisting of a Toll-like receptor, most preferably TLR4 or binding fragments thereof or multimeric arrangements thereof, CD14, MD2, TLR2 and LBP, and any combination thereof.

Claim 12 and 25 are drawn to the sedimented volume of the particles is at the most 70% of the volume of the column, such as at the most 60% of the volume of the column, e.g. at the most 50% of the volume of the column. Claim 15 is drawn to the flow rate of the blood through the column assembly is such that expansion ratio of the fluidized bed is at least 1.3, such as at least 1.5. Claim 16 is drawn to the steps (a), (b) and (c) being preceded by an initial step by which a substance is first injected into the blood stream of the mammal. Claim 19 is drawn to the stabilized fluidized bed is placed in line with a switch capable of being activated when a blood substance reaches a pre-set value, said blood substance is monitored by a device, said device is placed in line with the blood circulation, said device sending the activating signal to the switch when said value is reached.

Claim 27 is drawn to a method for the treatment of sepsis caused by Gram-negative or Gram-positive bacteria in a mammal by extracorporeal adsorption, said extracorporeal adsorption being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived from said Gram-positive bacteria, said method comprising the steps of: a) obtaining blood from said mammal, b) treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed, and c)



Art Unit: 1645

reinfusing the treated blood into the same mammal. Claim 28 is drawn to the method wherein the method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for the LPS portion of said Gram-negative bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed.

Lihme teaches an extracorporeal adsorption method for removing harmful substances in a mammal, being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column (page 25, lines 25-30), said particles being characterized by carrying an affinity specific molecule with a specific affinity for a harmful substance derived from Gram-positive bacteria (page 23-24, lines 29-9). Lihme teaches the method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed (page 9, lines 15-17). Lihme teaches extracorporeal adsorption by obtaining blood from a mammal; treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed; and reinfusing the treated blood into the same mammal (page 6,

Art Unit: 1645

lines 5-20). Lihme teaches the treated blood is capable of being reinfused into the same mammal (page 15, lines 22-26). Lihme teaches the adsorption column assembly being adapted for fluidized bed adsorption, in particular stabilized fluidized bed adsorption (page 9, lines 30-37).

Lihme teaches the particles have a density of at least 1.3 g/ml and a mean diameter in the range of 5-1000  $\mu\text{m}$ , and most preferred a density of more than 2.5 g/ml and a mean diameter in the range of 5-75  $\mu\text{m}$  (page 6, lines 20-29). Example 1A teaches the mammal being a human being. Lihme teaches the affinity specific molecule being immunoglobulins, peptides, oligonucleotides, receptor proteins, antibiotics, lectins, binding fragments and multimeric arrangement (page 19, lines 25-37). Lihme teaches two or more different affinity specific molecules are present on particles within the adsorption medium (page 8-9, lines 32-9). Lihme teaches the stabilized fluidized bed is placed in line with a switch capable of being activated when a blood substance reaches a pre-set value, said blood substance is monitored by a device, said device is placed in line with the blood circulation, said device sending the activating signal to the switch when said value is reached (page 16-17, lines 35-10).

Therefore Lihme teaches the invention as claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 2-8, 11-12, 15-18, 20-21 and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmerman et al., (US Patent 6,090,292 published July 18, 2000).

Claim 2 is drawn to an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by Gram-negative bacteria in a mammal, said extracorporeal adsorption method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed. Claims 3 and 17 are drawn to the treated blood is capable of being reinfused into the same mammal. Claims 4 and 26 drawn to the adsorption column assembly being adapted for fluidized bed adsorption, in particular stabilized fluidized bed adsorption. Claims 5 and 18 are drawn to the method wherein the particles have a density of at least 1.3 g/ml and a mean diameter in the

Art Unit: 1645

range of 5-1000  $\mu\text{m}$ , such as a density of at least 1.5 g/ml and a mean diameter in the range of 5-300  $\mu\text{m}$ , preferably a density of at least 1.8 g/ml and a mean diameter in the range of 5-150  $\mu\text{m}$ , and most preferred a density of more than 2.5 g/ml and a mean diameter in the range of 5-75  $\mu\text{m}$ . Claim 6 is drawn to the mammal being a human being.

Claims 7 and 20 are drawn to the affinity specific molecule is selected from the group consisting of peptides and receptor proteins. Claim 8 and 21 are drawn to two or more different affinity specific molecules are present on particles within the adsorption medium. Claims 11 and 24 are drawn to the affinity specific molecule being selected from the group consisting of a multimeric arrangements. Claim 12 and 25 are drawn to the sedimented volume of the particles is at the most 70% of the volume of the column, such as at the most 60% of the volume of the column, e.g. at the most 50% of the volume of the column. Claim 15 is drawn to the flow rate of the blood through the column assembly is such that expansion ratio of the fluidized bed is at least 1.3, such as at least 1.5. Claim 16 is drawn to the steps (a), (b) and (c) being preceded by an initial step by which a substance is first injected into the blood stream of the mammal.

Claim 27 is drawn to a method for the treatment of sepsis caused by Gram-negative or Gram-positive bacteria in a mammal by extracorporeal adsorption, said extracorporeal adsorption being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific

Art Unit: 1645

molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived from said Gram-positive bacteria, said method comprising the steps of: a) obtaining blood from said mammal, b) treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed, and c) reinfusing the treated blood into the same mammal. Claim 28 is drawn to the method wherein the method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for the LPS portion of said Gram-negative bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed.

Zimmerman et al., teaches an extracorporeal adsorption method for removing harmful substances caused by Gram-negative or Gram-positive bacteria in a mammal (col. 2, lines 25-28). Zimmerman et al., teach the method using an adsorption column assembly, comprising a column and an adsorption medium in the form of particles (col. 2, lines 43-48). Zimmerman et al., teach the sedimented volume of said particles being at the most 80% of the volume of the column (col. 3, lines 19-25). Zimmerman et al., teach the having particles carrying an affinity specific molecule with a specific affinity for Gram-negative bacteria wherein the method treats blood by passing the blood through

Art Unit: 1645

the adsorption column assembly (col. 2, lines 28-30) at such a flow rate that a fluidized bed of the particles is formed (col. 3, lines 25-32).

Zimmerman et al., teach the adsorption column assembly is adapted for fluidized bed adsorption, in particular stabilized fluidized bed adsorption (col. 4, lines 45-65).

Zimmerman et al., teach the particles have a density of at least 1.3 g/ml and a mean diameter in the range of 10-500 um (col. 2, lines 44-46). Zimmerman et al., teach the mammal being a human being (col. 2, lines 65-68). Zimmerman et al., teach the affinity specific molecule being a peptide, receptor protein, multimeric arrangements or two or more different affinity specific molecules are present on particles within the adsorption medium (col. 3, lines 33-35 and col. 5, lines 35-43). Zimmerman et al., teach the flow rate of the blood through the column assembly is such that expansion ratio of the fluidized bed is at least 1.3 (col. 4, lines 65-68). Zimmerman et al., teach a method wherein a heparin substance is first injected into the blood stream of the mammal (col. 3-4, lines 66-3).

Thus, Zimmerman et al., teach the instantly claimed inventions.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1645

9. Claims 2-7, 10, 16-18, 20, 23 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaber et al., (American Journal of Kidney Diseases. Vol 30, No 5, Suppl 4 (November), 1997: pages S44-S56).

Claim 2 is drawn to an extracorporeal adsorption method for removing harmful substances responsible of inducing sepsis caused by Gram-negative bacteria in a mammal, said extracorporeal adsorption method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed. Claims 3 and 17 are drawn to the treated blood is capable of being reinfused into the same mammal. Claims 4 and 26 drawn to the adsorption column assembly being adapted for fluidized bed adsorption, in particular stabilized fluidized bed adsorption. Claims 5 and 18 are drawn to the method wherein the particles have a density of at least 1.3 g/ml and a mean diameter in the range of 5-1000  $\mu\text{m}$ . Claim 6 is drawn to the mammal being a human being.

Claims 7 and 20 are drawn to the affinity specific molecule is selected from the group consisting of peptides and receptor proteins. Claim 16 is drawn to the steps (a), (b) and (c) being preceded by an initial step by which a substance is first injected into the blood stream of the mammal.

Claim 27 is drawn to a method for the treatment of sepsis caused by Gram-negative or Gram-positive bacteria in a mammal by extracorporeal adsorption, said extracorporeal adsorption being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for: i) the LPS portion of said Gram-negative bacteria, and/or ii) Gram-positive bacteria or harmful substances derived from said Gram-positive bacteria, said method comprising the steps of: a) obtaining blood from said mammal, b) treating the obtained blood by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed, and c) reinfusing the treated blood into the same mammal. Claim 28 is drawn to the method wherein the method being effected by an adsorption column assembly, said adsorption column assembly comprising a column and an adsorption medium in the form of particles, the sedimented volume of said particles being at the most 80% of the volume of the column, said particles being characterized by carrying an affinity specific molecule with a specific affinity for the LPS portion of said Gram-negative bacteria, said method comprising treating blood obtained from said mammal by passing the blood through the adsorption column assembly at such a flow rate that a fluidized bed of the particles is formed.



Art Unit: 1645

Jaber et al., teach extracorporeal adsorption method for treating gram-negative bacterial sepsis. Jaber et al., teach adsorbent-based blood purification being founded upon adsorption, which includes the removal of molecules by binding those molecules onto the surface of a material (page S44, col.2). Jaber et al., teach specific affinity molecules being antibodies coated onto micro spheres (page S53, col.1). See Table 1. Jaber et al., teach that polymyxinB has affinity for the Lipid A moiety of LPS from gram-negative bacteria (page S48, col. 2). Jaber et al., teach polymyxin B-Immobilized onto Sepharose bead with an affinity solid-phase column for the selective on-line removal of endotoxins during plasmapheresis (page S52, col. 1). Jaber et al., teaches using the affinity column device on rats in an on-line plasmapheresis with PMX-B sepharose beads having a diameter of 0.1 to 5um (page S52, col.1). Jaber et al., teach the endotoxin clearance rate was excellent (page S52, col.1). Jaber et al., also teach the use of polymyxin B-Immobilized macroporous cellulosic beads having a diameters of 60 to 80um, showing a more than 99.5% removal of endotoxins (page S52, col.1) Jaber et al., teach a flow rate of 200ml/min (page S53, col.1). Jaber et al., teach hemoperfusion methods wherein the flow rate was 80-100ml/min (page S50, col.2). Jaber et al., teach treating human whole blood or human plasma containing herapin or an anticoagulant on columns (page S49 col.2).

Therefore, Jaber et al., teach the instant claims.

***Conclusion***

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JaNa Hines whose telephone number is (571)272-0859. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JaNa Hines/  
Examiner, Art Unit 1645

/Mark Navarro/  
Primary Examiner, Art Unit 1645